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10/786,316

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Application Number 10/786,316

Attorney Docket Number

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Filing Date February 25, 2004 First Named Inventor Bharat B. Aggarwal Art Unit N/A **Examiner Name** Not Yet Assigned

AO-CLFR:215US

Total Number of Pages in This Submission	
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ENCLOSURES (Check all that apply)								
Fee Trans	mittal Form	Drawing(s)		After Allowance Communication to TC				
Fee	Attached	Licensing-related Papers		Appeal Communication to Board of Appeals and Interferences				
Amendme	nt/Reply	Petition		Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)				
After	Final	Petition to Convert to a Provisional Application		Proprietary Information				
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	SIGNATU	JRE OF APPLICANT, ATTO	RNEY, OR	AGENT				
Firm Name	FULBRIGHT & JAW	ORSKI L.L.P.						
Signature	Signature IIII							
Printed name	Melissa W. Acosta, I	Ph.D.						
Date	June 9, 2005		Reg. No.	45,872				

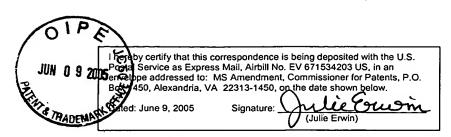
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Dated: June 9, 2005

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91001 (Nulle Erwin)



Docket No.: AO-CLFR:215US

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Bharat B. Aggarwal

Application No.: 10/786,316

Filed: February 25, 2004

Art Unit: N/A

For:

INHIBITORS OF RECEPTOR ACTIVATOR

OF NF-KB AND USES THEREOF

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

A copy of each reference on the PTO/SB/08 is attached.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

Application No.: 10/786,316 Docket No.: AO-CLFR:215US

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 06-2375, under Order No. AO-CLFR:215US.

Dated: June 9, 2005

Respectfully submitted,

Melissa W. Acosta, Ph.D. Registration No.: 45,872

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PTO/SB/08A (10-01)

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An				Application Number	10/786,316	
11	VFORMATION	V DI	SCLOSURE	Filing Date	February 25, 2004	
l s	TATEMENT I	BY A	APPLICANT	First Named Inventor	Bharat B. Aggarwal	
				Art Unit	N/A	
(use as many sheets as necessary)				Examiner Name	Not Yet Assigned	
Sheet	1	of	2	Attorney Docket Number	AO-CLFR:215US	

	U.S. PATENT DOCUMENTS										
Examiner Initials*	Cite No.1	Document Number Number-Kind Code² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear						
,	AA	US-5,843,678	12-01-1998	Boyle							
	AB	US-6,017,729	01-25-2000	Anderson et al.							
	AC	US-6,271,349	08-07-2001	Dougall et al.							
	AD	US-20030013170	01-16-2003	Aggarwal et al.							

	FOREIGN PATENT DOCUMENTS										
Examiner Initials*	Cite	Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant						
	No.1	Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY	Applicant of Cited Document	Passages or Relevant Figures Appear	T ⁶					
	BA	WO-2002092623	11-21-2002	Aggarwal et al.							
	ВВ	WO-199958674	11-18-1999	Anderson et al.							

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

¹ Applicant's unique citation designation number (optional). ² See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	CA	Akiba et al, "CD27, a Member of the Tumor Necrosis Factor Receptor Superfamily, Activates NF-κB and Stress-activated Protein Kinase/c-Jun N-terminal Kinase via TRAF2, TRAF5 and NF-κB-Inducing Kinase," The Journal of Biological Chemistry Vol. 273, No. 21, May 22, 1998, pgs 133353 - 13358.	
	СВ	Bharti et al, "Evidence that areceptor Activator of Nuclear Factor (NF)-κB Ligand Can Supress Cell Proliferation and Induce Apoptosis through Activation of a NF-κB-Independent and TRAF6-Dependent Mechanism," The Journal of Biological Chemistry Vol. 279, No. 7, February 13, 2004, pgs 6065 - 6076.	
	CC	Caldwell, J. "The Importance of Drug Metabolism Studies for Efficient Drug Discovery and Development," Xenobiotic Metabolism and Disposition Vol. 11 no. 1, 1996, pgs 119 - 126.	
	CD	Darnay et al, "Activation of NF-κB by RANK Requires Tumor Necrosis Factor Recpetor-Associated Factor (TRÁF) 6 and NF-κB-inducing Kinase: Identification of a Novel TRAF6 Interaction Motif," The Journal of Biological Chemistry Vol. 274, No. 12, March 19, 1999, pgs 7724 - 7731.	
	CE	Darnay et al, "Characterization of the Intracellular Domain of Receptor Activator of NF-κB (RANK)," The Journal of Biological Chemistry Vol. 273, no. 32, August 7, 1998, pgs 20551 - 20555.	
·	CF	Futaki et al, "Arginie-Rich Peptides: An Abundant Source of Membrane-Permeable Peptides Having Potential As Carriers for Intracellualr Protein Delivery," The journal of Biological Chemistry Vol. 276, No. 8, February 23, 2001, pgs 5836 - 5840.	
	CG	Galibert et al, "The Involvement of Multiple Tumor Necrosis Factor Receptor (TNFR) - associated Factors in the Signaling Mechanisms of Receptor Activator of NF-κB, a Member of the TNFR Superfamily," The Journal of Biological Chemistry Vol. 273, No. 51, december 18, 1998, pgs 34120 - 34127.	

Examiner	Date	
Signature	Considered	

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11	VEORMATION	1 DI	SCLOSURE	Filing Date	February 25, 2004	
5	STATEMENT I	BY A	APPLICANT	First Named Inventor	Bharat B. Aggarwal	
				Art Unit	N/A	
	(use as many sh	eets as	necessary)	Examiner Name	Not Yet Assigned	
Sheet	2	of	2	Attorney Docket Number	AO-CLFR:215US	

1011		
СН	Gravallese et al., "The role of TNF-receptor family members and other TRAF-dependent receptors in bone resorption," Arthritis Res., Vol. 3, 2000, pgs. 6-12.	
CI	Horwell, D.C., "The "Peptoid" Approach to the Design of Non-Peptide, Small Molecule	
	Agonists and Antagonists of Neuropeptides," Trends in Biotechnol Vol 13, 1995, pgs 132 - 134.	
CJ	Hsu et al, "Tumor Necrosis Factor Receptor Family Member RANK mediates Osteocast	
	Differentiation and Activation Induced by Osteoprotegerin Ligand," Proc. Natl. Acad. Sci USA Vol. 96, March 1999, pgs 3540 - 3545.	
СК	Kim et al, "Receptor Activator of NF-kB Recruits Multiple TRF Family Adaptors and Activates c-Jun N-terminal Kinase," FEBS Letts Vol. 443, 1999, pgs 297 - 302.	
CL	Lindgren et al., "Cell-penetrating peptides," TiPS, Vol. 21, 2000, pgs. 99-103.	
СМ		
CN	Oyajobi et al., "Therapeutic Efficacy of a Soluble Receptor Activator of Nuclear Factor κB-IgG Fc Fusion Protein in Suppressing Bone Resorption and Hypercalcemia in a Model of Humoral Hypercalcemia of Malignancy," Cancer Research, Vol. 61, 2001, pgs. 2572-2578.	
СО	Park et al, "Structural Basis for Self-Association and Receptor Recognition of Human TRAF2," Nature Vol. 398, April 8, 1999, pgs 533 - 538.	
СР	Pullen et al, "CD40 Signaling through Tumor Necrosis Factor Receptor-Associated Factors (TRAFs)," J. Biol. Chem Vol. 274 No. 20, 1999, pgs 14246 - 14254.	
CQ	Saragovi et al, "Loops and Secondary Structure Mimetics: Development and Applications in Basic Science and Rational Drug Design," Biotechnology Vol. 10, July 1992, pgs 773 - 778.	
CR	Shevde et al, "Estogens Suppress RANK Ligand-Induced Osteoclast Differentiation Via a Stromal Cell Independent Mechanism Involving c-Jun Repression," PNAS Vol. 97, No. 14, July 5, 2000, pgs 7829 - 7834.	
CS	Shin et al., "Identification of a negative regulator of tumor necrosis factor receptor-associated factor 6," Annual Meeting of the Federation of American Societies for Experimental Biology on Experimental Biol, 2001.	
СТ	Takayanagi et al., "T-cell-mediated regulation of aoteoclastogenesis by signaling cross-talk between RANKL and IFN-γ," Nature, 408, 2000.	
CU	Werneburg et al., "Molecular Characterization of CD40 Signaling Intermediates," J. Biol. Chem., Vol. 276, No. 46, 2001, pgs. 43334-43342.	_
CV	Wesche et al, "IRAK-M is a Novel Member of the Pell/Interleukin-1 Receptor-associated Kinase (IRAK) Family," The Journal of Biological Chemistry Vol. 274, No. 27, July 2, 1999, pgs 19403 - 19410.	
CW	Wexler et al, "Rationale for the Chemical Development of Antiotensin II Receptor Antagonists," Am. J. Hypertens Vol. 5, 1992, pgs 209S - 220S.	
СХ	Wong et al, "The TRAF Family of Signal Transducers Mediates NF-kB Activation by the TRANCE Receptor," The Journal of Biologicla Chemistry," Vol. 273, No. 43, October 23, 1998, pgs pgs 28355 - 28359.	
CY	Yasuda et al., "Identity of osteoclastogenesis inhibitory factor (OCIF) and osteoprotegerin (OPG); a mechanism by which OPG/OCIF inhibits osteoclatogenesis in vitro," Endocrinology, Vol. 139, No. 3, 1998, pgs. 1329-1337.	
CZ	Ye et al, "Distinct Molecular Mechanism for Initiating TRAF6 Signalling," Nature Vol. 418, July 25, 2002, pgs. 443 - 447.	
CA1	Yeh et al, "From Consensus Sequence Peptide to High Affinity Ligand, a "Library Scan" Strategy," The Journal of Biological Chemistry Vol. 276, No. 15, April 13, 2001, pgs 12235 - 12240.	
CB1	Zhang et al., "Tumor necrosis factor-a (TNF) stimulates RANKL-induced osteoclastogenesis via coupling of TNF type 1 receptor and RANK signaling pathways," J. Biol. Chem., Vol. 276,	

Examiner	Date	
Signature	Considered	

PTO/SB/08A (10-01)

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۱N	IFORMATION	1 DI	SCLOSURE	Filing Date	February 25, 2004		
S	TATEMENT I	BY λ	APPLICANT	First Named Inventor	Bharat B. Aggarwal		
				Art Unit	N/A		
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No. 1, 2001, pgs. 563-568.		•	

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Examiner	Date	
Signature	Considered	

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